3 RELATIVE SOURCE CONTRIBUTION

The relative source contribution (RSC) is an explicit parameter in USEPA's derivation of HHWQC. It applies only to HHWQC based on toxicological endpoints with a mode of action assumed to have a threshold (e.g., most non-cancer endpoints, non-linear cancer endpoints). The concept embodied by the RSC is that a person's total exposure to a chemical should not exceed the allowable exposure (i.e., the reference dose [RfD]). Exposure can come from a variety of pathways in addition to drinking of surface water or consumption of fish from waters regulated by HHWQC. The other pathways most frequently mentioned are exposures through inhalation and consumption of food. The RSC is used by USEPA to derive or establish the fraction of the RfD that can be apportioned to exposures from surface water when deriving HHWQC.

3.1 Origins of the RSC

The concept of the RSC has a long history. When developing national drinking water criteria in the mid-1970's as part of a collaboration with USEPA under the Safe Drinking Water Act (SDWA), the National Academy of Sciences (NAS) appears to have been one of the first to recognize that the combination of drinking water exposures regulated by drinking water standards combined with exposures from other sources (e.g., inhalation of air, consumption of food) could cause a person's total exposure to exceed the RfD (NAS 1977):

> *Since the calculation of the [acceptable daily intake (ADI)] values is based on the total amount of a chemical that is ingested, the ADI values calculated in this report do not represent a safe level for drinking water. However, a suggested no-anticipated-adverse-effect level has been calculated for these chemicals in drinking water using two hypothetical exposures (where water constitutes 1% and 20% of the total intake of the agent), and similar calculations can readily be made for other exposures.*

Though the NAS did not refer to the 1% and 20% as an RSC, the percentages serve the same purpose; assuming that either 1% or 20% of the acceptable daily intake (ADI) (the equivalent of the RfD) can be allotted to exposures from drinking water. The remainder (either 99% or 80%) was allotted to other sources of exposure.

Shortly thereafter, in 1980, the RSC concept was included by USEPA in the derivation of surface water quality criteria (USEPA 1980). For surface water quality criteria USEPA proposed to address exposures from other sources by subtracting exposures from diet and inhalation using the equation shown below (USEPA 1980).

$$C = ADI - (DT + IN) / [2\ L + (0.0065\ kg \times R)]$$

Where:

C is the criterion;
ADI is the acceptable daily intake (now called the reference dose (RfD));
2 L is the assumed daily water consumption;
0.0065 kg is the assumed daily fish consumption;
R is the bioconcentration factor (units of liters per kilogram [L/kg]);
DT is the estimated non-fish dietary intake; and
IN is the estimated daily intake by inhalation.

USEPA goes on to state "If estimates of IN and DT cannot be provided from experimental data, an assumption must be made concerning total exposure. It is recognized that either the inability to estimate DT and IN due to lack of data or the wide variability in DT and IN in different states may add an additional element of uncertainty to the criteria formulation process. In terms of scientific validity, the accurate estimate of the Acceptable Daily Intake is the major factor in satisfactory derivation of water quality." (USEPA 1980). Review of the criteria proposed by USEPA in 1980 indicates that for most, if not all compounds, both DT and IN were set to zero. In other words, non-fish dietary exposures and inhalation exposures were assumed to be zero. In 1991, USEPA discussed this assumption more explicitly stating "Where dietary and/or inhalation exposure values are unknown, these factors can be deleted from the above calculation." (USEPA 1991a).

Prior to 2015, HHWQC for most compounds were derived assuming the contribution from non-fish dietary sources and inhalation was assumed to be zero, the equivalent of setting the RSC to 1. The RSC was assumed to be 1 despite USEPA developing an extensive Decision Tree Approach (with 10 pages of supporting discussion) about the use of the RSC when deriving HHWQC (USEPA 2000). That decision tree distinguishes between RSCs derived using the subtraction method and the percentage method[4]. The subtraction method is essentially the same[5] as described in earlier USEPA HHWQC support documents (USEPA 1980, 1991a) and drinking water standard support documents (USEPA 1985, 1989a). What exactly USEPA intended when applying the percentage method is not as clear because, prior to 2000, HHWQC guidance referred to only the subtraction method. However, drinking water standards referred to both the subtraction method and the percentage method (USEPA 1985, 1989a).

In 1985, USEPA proposed national primary drinking water standards that used an RSC when deriving drinking water standards, though it was not yet referred to as the RSC at that time (USEPA 1985). In that proposal, USEPA describes two different approaches for deriving the equivalent of RSCs. When sufficient data about the magnitude of other sources of exposure are available, the drinking water standard is set by subtracting the exposure from other sources (e.g., air and food) from the RfD. This is referred to as the subtraction method. It is essentially the same as the subtraction method referred to by the USEPA (1980) for deriving HHWQC differing only in structure of the equations used to derive the standards/criteria. When sufficient data on exposure from sources other than drinking water are not available, USEPA proposes deriving the drinking water standard by multiplying the RfD by the assumed percentage of the RfD that is contributed by drinking water (USEPA 1985). This is referred to as the percentage method.

USEPA (1985) also establishes 20% as the assumed contribution of drinking water to allowable exposure when comprehensive data on exposure from other sources are not available. USEPA states that "this exposure factor is judgmental and is adjusted when mitigating information exists" and that "use of a 20% contribution is considered to be reasonably conservative." Four years later, USEPA also established a maximum RSC of 80% (USEPA 1989a). USEPA states "If data indicate that drinking water is responsible for a large part of total exposure to a chemical (i.e., 80 to 100 percent), EPA believes that it is prudent to allow for the contingency that exposure via air, food and other sources that may not be reflected in the available data is likely to occur. Utilizing the 80% "ceiling" for drinking water exposures ensures that the maximum contaminant level goal (MCLG) will be low enough to provide adequate protection for individuals whose total exposure to a contaminant is, due to dietary or other exposure, higher than currently indicated by available data. This approach, in effect, introduces an additional uncertainty factor…it ensures that the MCLG will result in no adverse effect with an adequate margin of safety." (USEPA 1989a).

When describing the subtraction and percentage methods, USEPA suggests that data about the magnitude of sources of exposure other than drinking water are likely available for inorganic compounds and are unlikely to be available for many organic compounds (USEPA 1985, 1989a).

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[4] In the subtraction method, the exposure supported by the RfD is allocated among various sources by first subtracting all exposure routes other than drinking water and fish consumption and then allocating the remainder of the RfD to drinking water and fish consumption. The percentage method is a simple ratio of exposure via drinking water and fish consumption to the total exposure.

[5] The equation is slightly different but the concept of reducing the portion of the RfD available for deriving HHWQC based on non-fish dietary and inhalation exposures is the same.

3.2 RSC Decision Tree

A detailed discussion of the application of the subtraction and percentage methods when developing HHWQC is provided in USEPA (2000). That discussion includes a recommended Decision Tree Approach for when each method is applicable. The scientific and policy basis for several of the decision points in the Decision Tree are worthy of more detailed consideration to determine whether the approach is applicable and relevant to individual States.

- The description of the subtraction approach is consistent with descriptions in prior USEPA guidance (USEPA 1980, 1985, 1989a, 1991a). However, the description of the percentage approach differs from previous descriptions presented in drinking water standard guidance (USEPA 1985, 1989a). When describing the percentage approach in 1989, USEPA states "When data did not exist, EPA then estimated drinking water's contribution at 20 percent of total exposure." (USEPA 1989a). In other words, when USEPA did not have information on the magnitude of exposure from other sources, it selected 20% as the default RSC. The description of the percentage method in USEPA (2000) assumes information about other sources is available. The percentage method is described as "This simply refers to the percentage of overall exposure contributed by an individual exposure source. For example, if for a particular chemical, drinking water were to represent half of total exposure and diet were to present the other half, then the drinking water contribution (or RSC) would be 50 percent." (USEPA 2000). This definition assumes information about total exposure is available. The presumption that information on total exposure is available is further reinforced by a recent description of the percentage method (USEPA 2015b, see Attachment C). Previous descriptions of the percentage method state the method is to be used when information on other exposure sources is absent. If total exposure can be quantified, then information on other sources must be available. If such information is available and is reliable enough to develop an estimate of total exposure, then the percentage method (at least as described prior to 2000) would not need to be used to estimate an RSC.
- Given the descriptions in the 2000 HHWQC guidance, the health protection achieved by the two alternative approaches to the percentage method differ. In the approach used to establish drinking water standards, where the contribution of drinking water to the RfD is simply set at a specific percentage, drinking water exposures can be as high as the set percentage, but will not exceed that percentage. As long as that percentage is less than 100% (i.e., the RSC is less than 1), drinking water exposures will not exceed the RfD. And as long as exposure from other sources is no more than the 80% of the RfD, total exposure will not exceed the RfD. In the approach described by USEPA (2000) where the RSC is determined by the percentage that surface water exposures represent of total exposure, relatively small surface water exposures will remain small. However, relatively large drinking water exposures will remain large (see Attachment C). As long as total exposure is less than the RfD, exposures from surface water will also be less than the RfD. However, it is possible for this application of the percentage method to result in total exposures that exceed the RfD. One example is a situation where total exposure is equal to the RfD, surface water exposures are a relatively large proportion of that total exposure and new toxicity data become available that lead to a decrease in the RfD such that the existing total exposure now exceeds the new RfD. Because the percentage that surface water comprises of total exposure remains the same (exposures did not change, only the RfD), the RSC remains

the same and can result in a situation where total exposure exceeds the RfD (see Attachment C). This is an example of where the percentage method would not meet the stated goal of using a RSC "…the purpose of the RSC is to ensure that the level of chemical allowed by a criterion or multiple criteria…will not result in exposure that exceed the RfD…" (USEPA 2000). States should recognize that unlike the subtraction method, the percentage may not meet the fundamental goal of the RSC under certain conditions.

- The Decision Tree Approach indicates that the subtraction method should not be used for compounds that have criteria or standards for other environmental media. That distinction was not raised when the two methods were discussed in drinking water standards guidance (USEPA 1985,1989a). Nor is it clear why the distinction is being made in the 2000 HHWQC guidance. USEPA states "When more than one criterion is relevant to a particular chemical, apportioning the RfD…via the percentage method is considered appropriate to ensure that the combination of health criteria, and thus the potential for resulting exposures, do not exceed the RfD…" (USEPA 2000). That statement fails to explain how applying the percentage method to HHWQC would keep total exposure from exceeding the RfD. The RSC is only applied to surface water criteria or drinking water standards. Apportioning the RfD in only one medium (e.g., surface water or drinking water) and not the others (e.g., air, foodstuffs) can still lead to the potential for total exposure to exceed the RfD. Each medium for which standards/criteria are based on an unapportioned RfD could by themselves have exposures equal to the RfD. When all exposures are combined, the RfD could be exceeded. Such an interpretation also assumes that concentrations in all environmental media are always equal to applicable criteria/standards. Given that criteria/standards are often enforced in a manner that leads to media concentrations well below concentrations allowed by criteria/standards (see Attachment G), the assumption that media concentrations will always be equal to the criteria/standards adds another uncertainty factor that may not be necessary. If data for the chemical in environmental media indicate that concentrations are lower than allowed by criteria/standards and are expected to remain that way, States should consider whether it is reasonable and necessary to use the more recent 2000 description of the percentage method and effectively assume concentrations are equal to criteria/standards, particularly if the enforcement methodology will continue to preclude such concentrations.
- The Decision Tree Approach also recommends evaluation of data adequacy and sufficiency. The associated discussion describes quite rigorous thresholds for data adequacy, though it does start out by recognizing application of professional judgment (USEPA 2000). Whether it represents professional judgment on USEPA's part or some alternative decision process to arrive at RSCs, it is important for States to recognize that some of the existing RSCs that differ from USEPA's default floor of 0.2 were derived prior to publication of the Decision Tree Approach and are unlikely to be consistent with all the data thresholds described therein. For example, when setting drinking water standards, USEPA uses a RSC of 0.8 for barium (USEPA 2016a). That RSC was derived by USEPA in 1985 (USEPA 1985). In that derivation, USEPA states "Little data are available on the level of barium in the U.S. food supply...Studies of four individuals indicated the dietary intake of barium ranged from 440 to 1,800 ug/day. The "average" value of 900 ug/day reportedly includes intake from beverages. The ICRP reports an "average" daily dietary intake of 750 ug/day for an adult male from food and fluids, of which 80 ug/day comes from drinking water. Based on these data, the diet contributes approximately 670 ug barium to the adult human intake

each day." (USEPA 1985). USEPA then goes on to use that estimate of exposure to derive the RSC of 0.8 for barium that is still used today. USEPA also uses a RSC of 0.4 when deriving the HHWQC and MCLG for antimony (USEPA 2002b, 1992). That RSC was derived in 1992 and is based on a survey of antimony in drinking water and a Food and Drug Administration (FDA) study of contaminants in food. Review of these studies should provide States a sense of the data requirements USEPA relies upon for HHWQC RSCs and the kind of deviations from data adequacy thresholds in the Decision Tree Approach that USEPA may find acceptable when deriving State-specific RSCs.

Note as well that inclusion of salmon in the FCR (discussed above in Sections 2.1 and 2.2) can lead to a "double counting" of potential exposure to a compound in the derivation of HHWQC if the RSC is used to account for exposures from consumption of fish such as salmon that accumulated their body burden of a compound while in the marine environment. The goal of the RSC is to account for exposures not affected by HHWQC. Including salmon increases the FCR and reduces the HHWQC. The potential exposure from consumption of salmon is accounted for by such inclusion. However, if HHWQC are further reduced through the application of a RSC to account for exposures of salmon in the marine environment, then the HHWQC is reduced further. That further reduction is not necessary because the exposure from such salmon was already addressed by the inclusion of salmon in the FCR used to derive the HHWQC. Such double counting can be prevented by either not including salmon in the FCR or not including exposures associated with consumption of salmon in the RSC.

3.3 Application of RSCs

When using RSCs to derive state-wide criteria, States should appreciate and carefully consider at least five points.

First, are RSCs needed at all? The concept embodied by the RSC was recognized by USEPA in 1980, but it was not until 2015, 35 years later, that USEPA included an RSC of less than 1 when deriving HHWQC for most compounds. USEPA has referred to these as an "additional uncertainty factor." As discussed in other sections of this document and attachments, numerous conservative assumptions are already used to estimate exposure and toxicity when deriving HHWQC. Is another one necessary? Have data come to light in those intervening 35 years to suggest that exposures from other sources have been increasing or are larger than USEPA and States have been assuming for the past 35 years and, therefore, is application of an RSC and an added uncertainty factor to account for such exposures necessary?

Second, if an RSC is needed, should it be developed using the subtraction or percentage method? The Decision Tree Approach in USEPA (2000) sets forth a series of conditions that lead to selection of one approach over the other. The basis for some of those conditions is unclear (such as the recommendation to use the percentage method if the compound is regulated in other environmental media) and should be carefully considered and the applicability to a particular State understood before deciding upon the method. Additionally, as noted above, under certain conditions, the percentage method may not meet the original goal of the RSC; to assure the total exposure from all sources remains below the RfD. Finally, USEPA also points out that situations may exist where the decision tree "is not practicable or may simply be irrelevant after considering the properties, uses, and sources of the chemical in question" and goes on to state "EPA endorses such flexibility…to choose other procedures that are more appropriate for setting

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health-based criteria and, perhaps, apportioning the RfD…as long as reasons are given as to why it is not appropriate to follow the Exposure Decision Tree approach and as long as the steps taken to evaluate the potential sources and levels of exposure are clearly described." (USEPA 2000).

Third, regardless whether the percentage or subtraction method is used to derive an RSC, should the default of 20% used by USEPA for most compounds be employed? As noted above under the first consideration, many more data are available now than were available 30 years ago on the potential exposure to many of the compounds for which HHWQC may be proposed. These data may indicate that exposures from other sources are lower than assumed by a default RSC of 20% (i.e., sources other than surface water contribute less than 80% of the RfD) and that a data-derived RSC is scientifically defensible and appropriate. Examples of such RSCs are provided in Attachment D.

Fourth, when deriving a State-specific RSC, must the data requirements set forth in USEPA (2000) be adhered to, or is the totality of data that have been collected on environmental concentrations of compounds in the past three decades (since USEPA [1985] raised the data-based distinction between the subtraction and percentage methods) sufficient to make well-informed assessments of exposure from the diet and air? USEPA (2000) contains rather extensive requirements for data to be considered usable when deriving a State-specific RSC. However, review of the data used by USEPA to derive RSCs for some drinking water standards, and in a few instances for HHWQC, suggests that those same data quality thresholds would not be met by several of the current RSCs that differ from the default of 20%. USEPA (2000) does note that a "case-by-case determination may be necessary" and that "data may, therefore, be adequate for some decisions and inadequate for others; this determination require some professional judgment (USEPA 2000).

Fifth, if a default RSC is determined to be appropriate, should USEPA's uniform range of default RSCs of 20% to 80% be used for all compounds? The original default floor and ceiling of 20% and 80%, respectively, were developed for drinking water standards, not surface water quality criteria (USEPA 1989a). Surface water quality criteria include both drinking water and dietary (fish consumption) exposure pathways. In other words, a portion of the dietary exposure accounted for the by the default RSC range of 20% to 80% used to establish drinking water standards is regulated by HHWQC. For bioaccumulative compounds, the portion of a person's total dietary exposure regulated by HHWQC may be quite large if high fish consumption rates are used to derive HHWQC[6]. States should consider whether the default RSCs developed for drinking water only exposures are applicable to HHWQC developed to regulate exposures from ingestion of surface water and consumption of fish from surface water.

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[6] Consider a simple example using the subtraction method where the total exposure is known and that exposure and the allowable exposure are both 100 milligrams per day (mg/day). Further, assume that drinking water contributes 25 mg/day, consumption of fish contributes 50 mg/day and consumption of other dietary items contributes 25 mg/day. The compound is not present in air. Therefore, inhalation does not contribute to total exposure. The amount of the RfD available for drinking water exposure is 25 mg/day (RfD – total dietary intake – inhalation; 100 – 75 – 0 = 25 mg/day) equivalent to an RSC of 0.25. The RSC for surface water exposure that includes exposures through ingestion of water and consumption of fish will be different. The portion of the dietary intake comprised of fish is regulated by the criterion and should not be subtracted from the RfD. For surface water, the amount of the RfD available for drinking water ingestion and fish consumption is 75 mg/day (RfD – non-fish dietary intake – inhalation; 100 – 25 – 0 = 75 mg/day) equivalent to a RSC of 0.75. This is a simple example pointing to what seems a common-sense realization that the default RSC for criteria regulating only one pathway (drinking water) should be different from the default RSC for criteria regulating multiple pathways (drinking water and fish consumption).

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